DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

Limacorporate S.p.A
Ms. Cheryl Hastings
Principal Consultant
P.O. Box 696
Winona Lake, Indiana 46590-696

Re: K110598
Trade/Device Name: SMR Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: August 5, 2011
Received: August 12, 2011

Dear Ms. Hastings:

This letter corrects our substantially equivalent letter of August 18, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown K110598

Device Name: SMR Reverse Shoulder System

Indications for Use:

## SMR Reverse Shoulder System
## Indications for Use

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy.
The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.
The components are intended for use in cemented and uncemented applications, as specified in the following table:

| COMPONENT | USE | |
|---|---|---|
| | Cemented | Uncemented |
| Cemented stems | X | |
| Cementless Finned stems | | X |
| Reverse Humeral Bodies | X | X |
| Reverse Liners | X | X |
| Glenospheres | | X |
| Connectors | | X |
| Metal Back Glenoid | | X |
| Bone Screws | | X |

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110598

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AUG 18 2011

# Summary of Safety and Effectiveness

Date: June 10, 2011

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

| Product | Product Code | Regulation and Classification Name |
|---|---|---|
| SMR Reverse Shoulder System | KWS | Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660 |

**Description:**

The SMR Reverse Shoulder System consists of a humeral stem, a reverse humeral body, a reverse liner, a metal-back glenoid, a glenosphere and a connector with screw. Bone screws are used for the fixation of the metal-back glenoid to the scapula. Humeral stems are provided for both cemented (cleared via 510(k): K100858) and cementless (cleared via 510(k): K101263) fixation as well as reverse humeral bodies (object of this submission). The SMR Reverse Shoulder System metal back glenoids and glenospheres are intended for uncemented press-fit use only with the addition of screws for fixation.

Two designs of humeral stems are available: the first one (cleared via 510(k): K100858) is intended for cemented use only while the second one (cleared via 510(k): K101263) is intended for uncemented use. The stems are provided with a male Morse taper to allow coupling with the reverse humeral bodies.

All reverse humeral bodies for SMR Reverse Shoulder Systems are made from Ti6Al4V (ASTM F1472 – ISO 5832-3). They are intended to be coupled by means of a Morse taper with the humeral stem; further stabilization is achieved with a screw that joins the humeral body to the stem. SMR reverse humeral bodies have a fixed cervico-diaphyseal angle of 150° to provide the correct varus-valgus alignment of the joint. The humeral body has a female taper for coupling with the reverse liner. Two versions of the SMR reverse liners are available: standard (available in Standard and Short sizes) and finned for trauma applications (fins with holes for tuberosities reconstruction provided).

Reverse liners are made from standard ultra-high molecular weight polyethylene (ASTM F648 – ISO 5834-2); they are coupled via the internal taper of the reverse humeral bodies. Two designs of reverse liners are available: standard and retentive (characterized

by deeper spherical concavity, higher lateral rim to provide a larger articulating surface and greater congruency between the liner and the glenosphere than the standard liners).

Three thicknesses are available: STD, +3mm and +6mm. As reported for standard liners, the choice of the thickness is made by the surgeon to ensure the appropriate tension and prevent laxity in the joint.

Metal-backed glenoids are made from Ti6Al4V (ASTM F1472 - ISO 5832-3). The surface of the metal-backed glenoid which comes in contact with bone is coated with Ti plasma spray coating. These devices are intended to be press-fitted into a hole drilled into the glenoid cavity during surgery; the peg surface has several wings to aid in fixation. Metal backed glenoids are available in four sizes (small-R, Small, Standard and Large).

The plate has curved surfaces to adapt to the spherical shape of the glenoid cavity. The plate is provided with holes to allow the insertion of screws to fix the device in the glenoid cavity: Small-R, Small and Standard glenoids have two holes while the Large size has four holes.

Glenospheres are made from CoCrMo alloy that conforms to ASTM F1537 – ISO 5832-12. Two different designs are available: a standard glenosphere that can be centered with respect to the glenoid component or eccentrical glenosphere to provide offset. Both designs have a spherical shape of 36mm diameter and articulate with the standard UHMWPE liners of the humeral body.

Glenospheres are intended to be coupled to the metal-back glenoid through the use of a connector manufactured of Ti6Al4V (ASTM F1472 – ISO 5832-3). It incorporates a double male taper: one side is connected to the glenosphere while the other is coupled with the glenoid component. To increase the solidity of the system, a screw is used to link the glenosphere to the glenoid component. The screw is inserted through a hole on the surface of the glenosphere, passing through the internal cavity of the connector and then screwed to the metal-backed liner. Two types of connectors are used depending on the metal backed glenoid component: Small-STD and Small-R.

**Intended Use:**

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The components are intended for use in cemented and uncemented applications, as specified in the following table:

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| COMPONENT | USE | |
|---|---|---|
| | Cemented | Uncemented |
| Cemented stems | X | |
| Cementless Finned stems | | X |
| Reverse Humeral Bodies | X | X |
| Reverse Liners | X | X |
| Glenospheres | | X |
| Connectors | | X |
| Metal Back Glenoid | | X |
| Bone screws | | X |

**Predicate Devices:**
Promos Reverse Shoulder System (Plus Orthopedics, K081016);
Inverse/reverse Shoulder System (Zimmer, K053274);
Delta Xtend Reverse Shoulder (DePuy, K091751).

**Comparable Features to Predicate Device(s):**

The SMR Reverse Shoulder System is similar to the predicate devices in terms of intended use, indications, design and materials. The SMR Reverse Shoulder System and the predicates are all intended for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy.
The SMR humeral stems are intended for cemented or uncemented use, depending on the design, as are the predicate humeral stems. Reverse bodies are intended for cemented or uncemented use, they follow the indication of the humeral stems. The SMR and predicate glenoid baseplates are all intended for uncemented use only with the use of bone screws for additional fixation.

Like the Promos Modular Shoulder System, the SMR Shoulder System provides modular humeral stem and humeral body components. The Inverse/reverse and Delta Xtend Shoulder Systems are designed as a one-piece humeral stem / body component and have humeral cups to host reverse liners. All the systems are provided with reverse liners and glenospheres of similar diameters that are intended to articulate together. In all the systems the glenospheres are fixed to the glenoid bone through the use of a glenoid baseplate (also called metal back glenoid).

The components of the SMR Shoulder System are manufactured from the same or similar materials as the predicate devices.

**Non-Clinical Testing:** The SMR Reverse Shoulder System has undergone fatigue testing to demonstrate both the strength of the humeral stem and the post-fatigue strength of the modular connections; and wear testing of the reverse liner and glenospheres. All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. The testing results demonstrated the device's ability to perform under expected clinical conditions.

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**Clinical Testing:** Clinical testing was not necessary to demonstrate substantial equivalence of the SMR Reverse Shoulder System to the predicate device(s).